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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,242	06/18/2002	Thomas Gilchrist	8830-20	1401

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/069,242

Applicant(s)

GILCHRIST ET AL

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 December 2004.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-7,9,10,12-16,18 and 19 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1,2,4-7,9,10,12-16,18 and 19 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

An amendment of 12/23/04 amended the specification and claims 1 and 19, and canceled claim 11.

Claims examined on the merits are 1, 2, 4-7, 9, 10, 12-16, 18 and 5 19, which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

Claims 18 and 19 are rejected under 35 U.S.C. 112, second 10 paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons in the previous office of 8/30/04, and for reasons herein.

Claim 18 is confusing and unclear as to the process required by 15 reciting only a single step of providing a substrate. More would be required to perform the process than merely providing the substrate of claim 1. It is uncertain as to the relationship of the tissue to the substrate and cells of claim 1. Is the substrate combined with tissue and culturing carried out, or are some other steps carried out.

20 Claim 19 is confusing and unclear in not having antecedent basis for an aqueous medium in line 2. It is uncertain as to the relationship of the aqueous medium to the tissue and substrate in claim 18, and it is uncertain as to steps used to deliver the metal ions or boron.

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***Response to Arguments***

Applicants urge that there is nothing confusing about claim 18. However, the claim is confusing by requiring a method without setting forth steps that will perform a method. Merely providing the  
5 substrate of claim 1 does not constitute a method having steps. There is no relationship between providing the substrate, and encouraging tissue growth provided by method steps that will cause the substrate to encourage tissue growth.

Applicants state that claim 19 has been amended to remove  
10 unclarity regarding antecedent basis. However, the claim is still unclear since the step recited has not been related by other method steps to encouraging tissue growth to make clear how the step of the claim functions to encourage tissue growth.

***Claim Rejections - 35 USC § 103***

15 Claims 1, 2, 4-7, 9, 10, 12, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burnie et al in view of Gilchrist et al (WO 98/54104), and if necessary in further view of Beaver et al (4,748,121) for reasons in the previous office action and for reasons herein.

20 The claims are drawn to a cell culture growth substrate comprising a water-soluble glass matrix having at least a portion of its surface coated with living cells and containing at least one metallic ion or boron-containing compound.

Burnie et al disclose using a water-soluble glass substrate in  
25 monolayer cell culture (paragraph bridging pages 244 and 245). The

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water-soluble glass is the same as presently claimed except for containing boron-containing compound.

Gilchrist et al disclose water-soluble glass fibers containing boron (page 8, lines 18-20) and silver ions (page 9, lines 8-13).

5 Beaver et al disclose immobilizing biochemically active material such as cells (col 3, lines 17-23) on porous glass fibers prepared from a composition containing silica, boric oxide, alkali metal oxide and aluminum oxide (paragraph bridging cols 5 and 6).

It would have been obvious to provide a compound containing boron  
10 or a metal ion in the soluble glass of Burnie et al in view of Gilchrist et al preparing soluble glass containing a metal ion or boron, and if needed in further view of Beaver et al disclosing preparing glass for immobilizing cells from a composition containing boron. Monolayer culture as disclosed by Burnie et al will result in  
15 the glass being coated with cells. Sodium in the glass of Burnie et al will provide a metallic ion required by claim 1 as an alternative to the boron-containing compound. Furthermore, Gilchrist et al (page 9, lines 8-36) would have suggested metallic ions in addition to sodium ions. The conditions of dependent claims would have been  
20 matters of choice depending on individual preference in view of the disclosures of the references. The glass of Burnie et al contains phosphorus pentoxide as in claim 5, and can be a phosphate glass (page 9, line 8-9) as in claim 4. The glass of Burnie et al also contains an oxide as in claims 6 and 7, and the glass will inherently have a  
25 dissolution rate as in claim 9 and enable controlled release as in

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claim 10. Gilchrist et al (page 4, line 32), as well as Burnie et al (page 244, right col, third complete paragraph), and if needed Beaver et al suggest fibers as in claim 12. The methods of claims 18 and 19 are suggested by Burnie et al and Gilchrist et al disclosing the glass dissolving, and Gilchrist et al disclosing the release of silver. Selecting an amount of metal ion release as in claim 19 would have been a matter of individual preference. Moreover, Gilchrist et al suggest (page 9, lines 30-31) the amount of metal ion release as in claim 19.

10

***Response to Arguments***

Applicant's arguments filed 12/23/04 have been fully considered but they are not persuasive.

It is granted that Burnie et al does not disclose metal ions to provide a function as presently claimed. However, when Gilchrist et al is considered, providing a metal ion such as silver in the glass of Burnie et al that is released and is antimicrobial would have been obvious. The rejection is not based on using the materials of Gilchrist et al as a culture substrate, but on incorporating metal ions suggested by Gilchrist et al in the substrate of Burnie et al. The glass of Gilchrist et al is antimicrobial (page 16, lines 2-3), and this is apparently due to the controlled release of silver (page 9, line 12). It would have been obvious to provide silver in the glass of Burnie et al to provide release of the silver as suggested by Gilchrist et al. Note that Gilchrist et al disclose that it is known

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to provide release of metal ions at a wound site (page 1, lines 17-20). A metal ion such as silver is well known to be antimicrobial.

***Claim Rejections - 35 USC § 103***

Claims 13-16 are rejected under 35 U.S.C. 103(a) as being  
5 unpatentable over the references as applied to claims 1, 2, 4-7, 9, 10, 12, 18 and 19 above, and further in view of Ducheyne et al (5,811,302) for reasons in the previous office.

Claim 13 requires glass fibers sintered together to form a mat. Claims 14 requires glass particles which are sintered together in  
10 claim 15 and are of a specific size in claim 16.

Ducheyne et al disclose (col 4, lines 1-10) sintering glass particles to form a substrate for cell culture.

It would have been obvious to form the glass of Burnie et al, when modified as set forth above, as a sintered non-woven mat or  
15 sintered particles in view of Burnie et al disclosing (page 244, right col in the paragraph noted above) various forms including powder, fiber and woven cloth, and Gilchrist et al disclosing glass wool (page 4, line 15), and Ducheyne et al disclosing sintering glass particles. A powder will have a particle size within the range of claim 17.

20 ***Response to Arguments***

Applicants assert that even if the '302 patent is combined with the other references, the invention is not provided. However, providing a metal ion that is antimicrobial is suggested by the references applied above.

25 ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

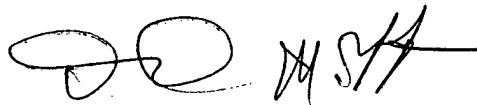
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 751-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff  
Primary Examiner  
Art Unit 1651

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DMN  
4/29/05